

September 4, 2018

BY E-MAIL & U.S. MAIL

Ms. Michelle Ramirez
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-12B
Sacramento, CA 95812-4010

Re: Proposal to Modify Proposition 65 Listing of "ethanol in alcoholic beverages"

Dear Ms. Ramirez:

The North American Meat Institute, which Dentons represents, respectfully requests that the Office of Environmental Health Hazard Assessment ("OEHHHA") not move forward with its August 3 proposal to revise the listing of "ethanol in alcoholic beverages" to "alcoholic beverages" (the "Listing Proposal"). The North American Meat Institute ("NAMI" or the "Institute"), which has significant concerns regarding Labor Code listings of foods, offers the following reasons for its request:

- Proposition 65 governs and regulates "chemicals" such as ethanol. It does not and should not regulate "substances" that are not well-defined chemicals.
- "Alcoholic beverages" is a category of substances that includes beverages that contain alcohols other than ethanol, such as methanol. There is no indication that the International Agency for Research on Cancer ("IARC") intended to include beverages other than those that contain ethanol in its cancer classification.
- Alcoholic beverages do not give rise to workplace exposures. Thus, they should not be listed via the Labor Code listing mechanism.
- The Director of Industrial Relations has not listed alcoholic beverages pursuant to the Labor Code, which is further evidence that alcoholic beverages cannot and should not be listed pursuant to the Labor Code listing mechanism.
- Changing the listing in the manner OEHHHA proposes would substantially complicate the process for identifying a no significant risk level ("NSRL").
- The most accurate reading of IARC Monograph 100E is that IARC is concerned with the presence of ethanol, not with methanol or other components of alcoholic beverages; and,

- OEHHA offers no explanation or reasoning as to what beverages would be covered by the new listing that are not covered by the old listing, making the need for this change unexplained and unsubstantiated.

I. Proposition 65 regulates “chemicals”, not “substances” that are not “chemicals”

OEHHA's proposed change to the Proposition 65 list of regulated chemicals is presented by OEHHA as a broadening of the listing of alcoholic beverage substances: “OEHHA has determined that the existing listing should be modified to reflect IARC's broader classification.” Thus, this proposed action would be a “listing” of the items not previously covered by the new “broader classification.”

Because OEHHA does not identify the chemical or chemicals that it is proposing to list through this Listing Proposal, the proposal is not authorized by the Proposition 65 statute and is not a proper agency action. The purported statutory authority for the Listing Proposal is section 25249.8(a) of the California Health and Safety Code, which states:

§ 25249.8. List of chemicals known to cause cancer or reproductive toxicity

(a) On or before March 1, 1987, the Governor shall cause to be published a list of *those chemicals* known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).

(emphasis in text added).

The title of this section and its first sentence make it clear that listings can include substances that are chemicals, but cannot include substances that are not chemicals. OEHHA's proposal is not consistent with the requirements of Proposition 65 because it does not identify any specific chemical. The key provisions of Proposition 65, the discharge prohibition and the warning requirement, reinforce this point -- they apply only to “chemicals” and do not mention “substances.” Cal. Health & Safety Code §§ 25249.5, 25249.6. Since a “substance” that is not a “chemical” would not trigger a warning requirement or a discharge prohibition, it is most logical and consistent with Proposition 65 for the listing of “substances” to be limited to substances that are well defined chemicals. Consistent with this interpretation, the list of items regulated by Proposition 65 is properly titled and described as a list of “chemicals.” 27 CCR § 27001.

II. Listing “Alcoholic Beverages” would be overbroad

The New Oxford Dictionary for Scientific Writers and Editors (2nd ed. 2009), like many other scientific dictionaries, defines alcohol as “any of a class of organic compounds containing the hydroxyl group -OH directly joined to a carbon atom.” There are dozens of common alcohols, including monohydric alcohols (e.g., ethanol, methanol), polyhydric alcohols (e.g., mannitol, sorbitol), unsaturated aliphatic alcohols (e.g., allyl alcohol), and alicyclic alcohols (e.g., menthol). From a scientific perspective, and based on OEHHA's statement that the Listing Proposal represents a “broadening” of the listing, the term “alcoholic beverages” would include beverages containing ethanol, methanol and other alcohols. This would make the listing overbroad. Beverages that contain methanol, such as certain fruit juices, were not analyzed by IARC and should not be subject to Proposition 65. IARC Monograph 100E only mentions methanol as a contaminant once, not as a subject of evaluation for carcinogenicity. Reading Monograph 100E overall, it

is obvious that IARC was focused on ethanol and its metabolites; there is no reason to, need to or justification to change the current listing.

III. “Alcoholic Beverages” do not create workplace exposures, and thus should not be listed pursuant to the Labor Code listing mechanism.

The Listing Proposal identifies Labor Code Section 6382(b)(1) as the basis for listing “alcoholic beverages.” Labor Code Section 6382(b)(1) does not apply to alcoholic beverages because it is part of the Hazardous Substances Information and Training Act (“HSITA”), California Labor Code Sections 6360-6399.7, and HSITA is specifically limited to workplace exposures. HSITA is designed to ensure the transmission of “necessary information to employees regarding the properties and potential hazards of hazardous substances *in the workplace*.” Cal. Labor Code § 6361(b) (emphasis added). HSITA only applies to “hazardous substances which are present in the workplace as a result of workplace operations in such a manner that employees may be exposed under normal conditions of work or in a reasonably foreseeable emergency resulting from workplace operations.” Cal. Labor Code § 6362. HSITA specifically does not “apply to hazardous substances contained in . . . Products intended for personal consumption by employees in the workplace, or consumer products packaged for distribution to, and use by, the general public.” Cal. Labor Code § 6365. Alcoholic beverages fall squarely within these exclusions from HSITA. Accordingly, OEHHA does not have statutory authority to undertake this listing and should not do so.

IV. “Alcoholic Beverages” have not been listed by the Director of Industrial Relations, as required by HSITA, and thus should not be listed pursuant to the Labor Code listing mechanism.

The Director of Industrial Relations is required by HSITA to “establish a list of hazardous substances and . . . make the list available to manufacturers, employers, and the public.” Labor Code section 6382, the section referenced in Proposition 65, governs the creation of the hazardous substance list. The entirety of Section 6382 must be considered when evaluating the scope of the Labor Code listing mechanism in Section 25249.8(a) of Proposition 65. In relevant part, Section 6382 provides:

6382. The director shall prepare and amend the list of hazardous substances according to the following procedure:

(a) Any substance designated in any of the following listings in subdivision (b) shall be presumed by the director to be potentially hazardous and shall be included on the list; provided, that the director shall not list a substance or form of the substance from the listings in subdivision (b) if he or she finds, upon a showing pursuant to the procedures set forth in Section 6380, that the substance as present occupationally is not potentially hazardous to human health; and provided further, that a substance, mixture, or product shall not be considered hazardous to the extent that the hazardous substance present is in a physical state, volume, or concentration for which there is no valid and substantial evidence that any adverse acute or chronic risk to human health may occur from exposure.

(b) The listings referred to in subdivision (a) are as follows:

(1) Substances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).

The Director has not added “Alcoholic beverages” to the HSITA list of hazardous substances. This is further evidence that this substance is not within the scope of HSITA and has been excluded from section 6382(b)(1) by operation of the limitations in sections 6362 and 6365 of the Labor Code. Proposition 65 listings pursuant to Health and Safety Code Section 25249.8(a) and Labor Code Section 6382(b)(1)

should be limited to those chemicals that the Director of Industrial Relations has added to the list of hazardous substances that Labor Code Section 6382 creates.

V. Changing the listing from its current focus on ethanol in alcoholic beverages is not practical because it would dramatically complicate calculation of a no significant risk level.

While the IARC Monograph focuses on ethanol, a listing of “alcoholic beverages” would appear to bar setting a NSRL based on ethanol levels. This, in turn, would require separate NSRLs to be established for each type of alcoholic beverage. Yet, the discussion in the Monograph and the data provided is not adequate to conclude that IARC reviewed all alcoholic beverages or any specific alcoholic beverage beyond the ethanol content. IARC analyzed ethanol and its metabolites, not each and every alcoholic beverage. Re-casting this listing would run counter to the establishment of a NSRL, an important element of Proposition 65, with no stated benefit for doing so.

VI. The most accurate reading of Volume 100E is that IARC’s analysis focused on ethanol.

Reading Monograph 100E overall, it is obvious that IARC was focused on ethanol and its metabolites; thus, there is no reason to, need to or justification to change the current listing. In fact, the first section of IARC Monograph 100E on Consumption of Alcoholic Beverages is entitled, “Types and ethanol content of alcoholic beverages.” Monograph 100E describes the types of alcoholic beverages as beer, wine and spirits:

The predominant types of commercially produced alcoholic beverages are beer, wine and spirits. Basic ingredients for beer are malted barley, water, hops and yeast. Wheat may be used. Nearly all wine is produced from grapes, although wine can be also made from other fruits and berries. Spirits are frequently produced from cereals (e.g. corn, wheat), beet or molasses, grapes or other fruits, cane sugar or potatoes. Main beverage types (i.e. beer, wine and spirits) may be consumed in combination with each other to fortify the strength of an alcoholic beverage (e.g. fortified wine, in which spirits are added to wine) (WHO, 2004).

IARC Monograph 100E (2012), p. 373.

This description of alcoholic beverages is not materially different from the description in Monograph 96, on which the current listing is based. IARC Monograph 96 (2010), p. 41.

IARC Monograph 100E contains an entire section devoted to the ethanol content of alcoholic beverages:

1.1.2 Ethanol content of alcoholic beverages

Percentage by volume (% vol) is used to indicate the ethanol content of beverages, which is also called the French or Gay-Lussac system. Alcohol content differs according to the main beverage type and may also vary by country. Commonly, 4–5% vol are contained in beer, about 12% vol in wine and about 40% vol in distilled spirits. However, lower or higher ethanol content in alcoholic beverages is also possible. The ethanol content in beer can range from 2.3% vol to over 10% vol (lower alcohol content in home- or locally produced alcoholic beverages such as sorghum beer), in wine from 8 to 15% vol, and in spirits from 20% vol (aperitifs) to well over 40% vol (e.g. 80% vol in some kinds of absinthe). There is a trend in recent years towards higher (13.5–14.5%) alcohol volume in consumed wines, associated with technology advances and increasing proportion in overall consumption of wines produced outside the traditional winegrowing regions of Europe (IARC, 2010). To calculate the amount of ethanol contained in a specific drink, the amount (e.g.

ml) of alcoholic beverage consumed for each type of beverage (e.g. a 330-mL bottle of beer) is multiplied by the percentage of alcohol by volume, i.e. the proportion of the total volume of the beverage that is alcohol (e.g. $(330 \text{ mL}) \times (0.04) = 13.2 \text{ mL}$ of ethanol in a bottle of beer). Conversion factors may be used to convert the volume of alcoholic beverage into grams of ethanol, or volumes of alcohol may be recorded in 'ounces'. Conversion factors for these different measures (WHO, 2000) are as follows:

- 1 mL ethanol = 0.79 g
- 1 UK oz = 2.84 cL = 28.4 mL = 22.3 g
- 1 US fluid oz = 2.96 cL = 29.6 mL = 23.2 g

IARC Monograph 100E (2012), pages 373-74.

IARC Monograph 96 is the same in the relevant respects. IARC Monograph 96 (2010), page 42.

Ethanol is the only alcohol mentioned in this section of the two IARC monographs. The calculations above are all based on the specific gravity of ethanol (0.79 g/mL). It could not be more clear that IARC is identifying alcoholic beverages that contain ethanol, as it did in 2010 and as OEHHHA acted upon in 2011.

VII. OEHHHA's proposal is not adequately explained

OEHHHA's "determination" constituting the basis for this proposal totals six lines; it states:

IARC Monograph volume 96 (IARC, 2010) states:

Alcoholic beverages are carcinogenic to humans (Group 1)

In its online listing of classifications, IARC also lists alcoholic beverages as Group 1, carcinogenic to humans (IARC, 2018), also referencing Monograph 100E (IARC, 2012). Therefore, OEHHHA has determined that the existing listing should be modified to reflect IARC's broader classification by striking the words "ethanol in" from the listing.

IARC Monograph volume 96 was the basis for OEHHHA's 2011 listing of ethanol in alcoholic beverages. This volume 96 statement demonstrates that IARC has from time to time used the shorthand description of "alcoholic beverages" but has not changed its fundamental analysis, as noted by OEHHHA in the 2011 listing of ethanol in alcoholic beverages, that ethanol in alcoholic beverages is the basis for the listing. The fact that certain online listings and certain passages in the Monographs do not specifically mention ethanol does not mean that IARC has substantively broadened its listing since 2011. Quite the contrary, IARC has been consistent, as OEHHHA's reference to volume 96 demonstrates.

Although OEHHHA's determination identifies IARC as having made a "broader determination," OEHHHA does not explain what items would be covered by the "broader determination" that are not covered by the existing determination or how one derives that conclusion from the substance of the IARC Monograph. The Institute submits that none can be found in the IARC Monographs and that it is OEHHHA's burden to identify what would be covered by this broader listing that is not covered by the prior listing in order to adequately explain and justify this proposed action. OEHHHA has not done so; it has issued no findings or determination explaining what is covered by this "broader determination" and where IARC made the "broader determination"; it has not explained why the existing listing is not adequate or representative of

the current IARC analysis. OEHHA's determination is so brief and conclusory that it is without substance and it offers no glimpse of the agency's actual reasoning or analysis.

Conclusion

The North American Meat Institute has significant concerns regarding the listings of foods based on the Labor Code listing mechanism. For the reasons described above, OEHHA should not take the action it proposed on August 3. The Institute requests the opportunity to meet with OEHHA to discuss this further after OEHHA has had an opportunity to review and consider these comments.

Sincerely,



Gary M. Roberts

cc: Dr. Lauren Zeise
Ms. Carol Monahan-Cummings
Mr. Gordon Burns
Mr. Mark Dopp